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Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/963,227	11/03/97	AHLUWALIA	G 00216/289002

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HM42/1006

EXAMINER

HARRISON, R

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 10/06/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/963,227

Applicant(s)  
Ahluwalia et al

Examiner  
Robert H. Harrison

Group Art Unit  
1616



☒ Responsive to communication(s) filed on Mar 30, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-77 is/are pending in the application.

Of the above, claim(s) 2-7, 9-20, 30-41, and 44-74 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 8, 21-29, 42, 43, and 75-77 is/are rejected.

☒ Claim(s) 27, 75, and 77 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1616.

Claims 1-77 are in the case.

Claims 1-77 are generic to a plurality of disclosed patentably distinct species comprising one patentably distinct species (or independent invention) per MPEP § 803, 809.02(d) (Markush group claim practice, separate and burdensome fields of search required), select one from each of: the encompassed ultimate species of the nonsteroidal suppressor of angiogenesis selected from one of those set forth in the instant specification. Each nonsteroidal suppressor of angiogenesis requires a separate and burdensome search in one or more of the subclasses of Class 514, there being no home or subclass for the enumerable nonsteroidal suppressor of angiogenesis as set forth in the instant claims.

Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species even though this requirement is traversed.

Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicants are further required to identify the claims that correspond to the election as well as those that do not, even if the requirement is traversed.

During a telephone conversation with Robert C. Nabinger on March 21, 1996 a provisional election was made with traverse to prosecute the invention of mycophenolic acid as the nonsteroidal suppressor of angiogenesis, claims 1, 8, 21-29, 42 and 43. Affirmation of this election must be made by applicants in responding to this Office action. Claims 2-7, 9-20, 30-41 and 44-74 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The election in the parent carries forward into the instant application.

Applicants are advised that should claim 27 be found allowable, claim 77 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the

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other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 27 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 77. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 8, 21-26, 42, 43, 75 and 76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For a detailed rationale of why, please see pages 4 and 5 of the previous Office action mailed as of July 8, 1996 or Paper No. 4.

Claim 75 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 75 does not further limit the subject matter of any

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of the claims referred to in the alternative since all these claims depend from the generic claim 1 which includes this limitation. Please note it is not clear what is meant by "00" which follows the period in claim 75.

The Declaration under 37 CFR 1.132 filed March 30, 1998 is insufficient to overcome the rejection of claims 1, 8, 21-26, 42, 43, 75 and 76 based upon 35 U.S.C. § 112, first paragraph as set forth in the last Office action because:

The evidence or data submitted in the Declaration fails to establish through objective evidence that the patent relied upon for non-enablement is in error since the positions taken in the Declaration appear to be an opinion and are not set forth with supporting facts. While the Examiner will accept the golden Syrian hamster as a suitable model for human beard hair growth, see item 4 in the Declaration as well as page 9, second full paragraph which states this. However, this testing is not commensurate in scope with the claims. Applicants have provided no factual basis to refute the conclusions drawn to patentees. In fact, applicants appear to be taking both sides of the argument. They are attacking the conclusions of patentees based upon insufficient testing but applicants urge that the alleged same insufficient testing should be the basis for assuming mycophenolic acid should also reduce hair growth in humans that is not androgen-stimulated. See item 4 in the Declaration. The

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Examiner sees no basis to support such an allegation. Since patentees have already disclosed that the claimed active is effective for reducing hair growth, it is incumbent upon applicants to rebut such a case. It is the opinion of the Examiner that such has not been done for the full scope of the claims.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of enablement fails to outweigh the evidence of non-enablement.

Applicants' arguments filed March 30, 1998 have been fully considered but they are not deemed to be persuasive.

Applicants traverse, arguing that certain claims, namely 2-7 and 8-20 "potentially" literally cover using a composition containing the claimed active in the claimed methods. This argument is respectfully traversed since there is no proof of this. The Examiner sees no factual basis for this conclusion and applicants have not provided any evidence for this. The Examiner would respectfully refer applicants to the International Search performed and mailed as of October 10, 1996 where it was found that the claims were not clear and concise and encompassed an enormous amount of products. A complete search is not possible on economic grounds guided by the spirit of the application in the inventive concept as disclosed in the descriptive part of this present application. The search has been based on the

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Examples. The Examiner sees no error in this conclusion and it is not clear from this record how the claimed active is embraced within the functional limitations set forth in the subject claims that applicants traverse. If applicants have such facts to support not a potential but an actual covering of these claims of the claimed active, then they should come forward with such factual basis.

The following is the Examiner's suggestion of allowable subject matter: If applicants were to insert "mycophenolic acid" into the base claims which also include the limitation that the hair growth comprises androgen-stimulated hair growth on the beard in a human, then such would be deemed as allowable.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Any inquiry concerning this communication should be directed to Robert H. Harrison at telephone number (703) 308-2422.

*Robert H. Harrison*  
Robert H. Harrison  
Primary Examiner  
Art Unit 1616

RHHarrison:cdc  
October 5, 1998